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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,840	03/13/2001	Gregory R. Mundy	10274-034001	4957

7590

06/17/2002

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EXAMINER

GAMBEL, PHILLIP

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/17/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/805840

Applicant(s)

MUNDY

Examiner

GAMBEL

Art Unit

1644

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

### DETAILED ACTION

1. The examiner of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Technology Center 1600.
2. Prior to setting forth the restriction requirement, it is pointed out that the claims are drawn to patentably distinct methods relying upon patentably distinct products. The methods rely upon (1) alpha4-specific antibodies, (2) alpha4 ligand-specific antibodies, (3) alpha4beta7-specific antibodies, (4) (VCAM-1-specific antibodies and (5) small molecules, which differ in structure and modes of action to such an extent and require non-coextensive searches to such an extent that they are considered separately patentable. Therefore, the restriction will be set forth for each of the various groups, irrespective of the format of the claims, because these are not proper species. Applicant is invited to clearly elect a single Group as it reads on a particular therapeutic agent and to provide an appropriate claim that reads on the elected invention.
3. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
  - I. Claims , 1, 2, 4, 5, 7, 9, drawn to methods of treating multiple myeloma with alpha4-specific antibodies, classified in Class 424, subclass 130.1.
  - II. Claims 1, 3-5, 7, 9, drawn to methods of treating multiple myeloma with alpha4 ligand-specific antibodies, classified in Class 424, subclass 130.1.
  - III. Claims 1, 4, 5, 7, 9, drawn to methods of treating multiple myeloma with alpha4beta7-specific antibodies, classified in Class 424, subclass 130.1
  - IV. Claims 1, 5-7, 9 drawn to methods of treating multiple myeloma with VCAM-1-specific antibodies, classified in Class 424, subclass 130.1.
  - V. Claims 1, 8, 9 , drawn to methods of treating multiple myeloma with small molecules, classified in Class 514, subclass 2.
  - VI. Claims 10, 11, 14, 16, 18, 19, drawn to methods of inhibiting bone resorption associated with bone marrow tumors with alpha4-specific antibodies, classified in Class 424, subclass 130.1.
  - VII. Claims 10, 12, 14, 16, 18, 19, drawn to methods of treating inhibiting bone resorption associated with bone marrow tumors with alpha4 ligand-specific antibodies, classified in Class 424, subclass 130.1.
  - VIII. Claims 10, 13, 14, 16, 18, 19, drawn to methods of treating inhibiting bone resorption associated with bone marrow tumors with alpha4beta7-specific antibodies , classified in Class 424, subclass 130.1.

- IX. Claims 10, 14-16, 18, 19, drawn to methods of treating inhibiting bone resorption associated with bone marrow tumors with VCAM-1-specific antibodies, classified in Class 424, subclass 130.1.
- X. Claims 10, 17, 18, 19, drawn to methods of treating inhibiting bone resorption associated with bone marrow tumors with small molecules, classified in Class 514, subclass 2.
- XI. Claims 20, 21, 24, 26, 28, 29, drawn to methods of treating a disorder characterized by osteoclastogenesis with alpha4-specific antibodies, classified in Class 424, subclass 130.1.
- XII. Claims 20, 22, 24, 26, 28, 29, drawn to methods of treating a disorder characterized by osteoclastogenesis multiple myeloma with alpha4 ligand-specific antibodies, classified in Class 424, subclass 130.1.
- XIII. Claims 20, 23, 24, 26, 28, 29, drawn to methods of treating a disorder characterized by osteoclastogenesis with alpha4beta7-specific antibodies , classified in Class 424, subclass 130.1.
- XIV. Claims 20, 24-26, 28, 29 drawn to methods of treating a disorder characterized by osteoclastogenesis with VCAM-1-specific antibodies, classified in Class 424, subclass 130.1.
- XV. Claims 20, 27-29 , drawn to methods of a disorder characterized by osteoclastogenesis treating with small molecules, classified in Class 514, subclass 2.

4. Inventions I-XVI are different methods, which require patentably distinct ingredients. Therefore, they are patentably distinct. The claimed methods employ various alpha4 subunit inhibitors which are distinct because their structures and physicochemical properties are different, which require non-coextensive searches. These alpha4 subunit inhibitors are different with respect to biochemical properties; including primary, secondary and tertiary structure. These molecules do not share a substantial structural feature essential to a common utility. Therefore, they are patentably distinct.

Applicant is invited to provide information concerning the overlap or inference of the claimed methods as they read on the preambles of "treating multiple myeloma", "treating inhibiting bone resorption associated with bone marrow tumors", "methods of treating a disorder characterized by osteoclastogenesis".

5. Because these inventions are distinct for the reasons given above and the search required for any Group from Groups I-XV is not required for any other group from Groups I-XV and Groups I-XV have acquired a separate status in the art because the searches are not co-extensive and encompass divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.



Phillip Gambel, PhD.  
Primary Examiner  
Technology Center 1600  
June 6, 2002